M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: October 15, 1999

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Electronic Abbreviated New Drug Applications

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Guidance & Future Direction

Presented for: UMBC Advanced Electronic Submission Training for Industry

Date Presented: 10/15/1999

Presented by: Richard Sponaugle

Number of Pages: 10

Melissa Lamb

Attachment

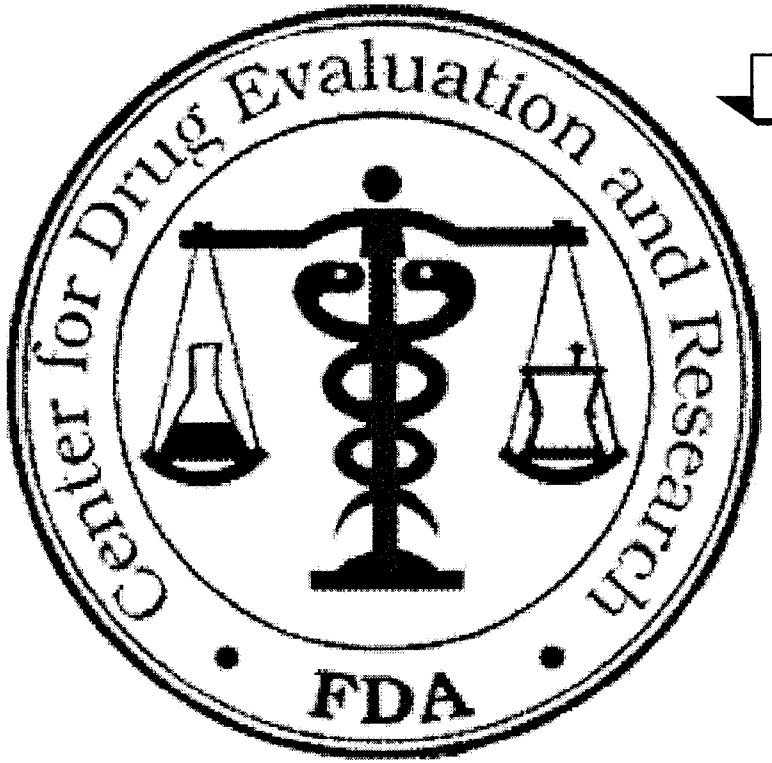
90S-0308

M 674

Electronic Abbreviated New Drug Applications

Discussion:

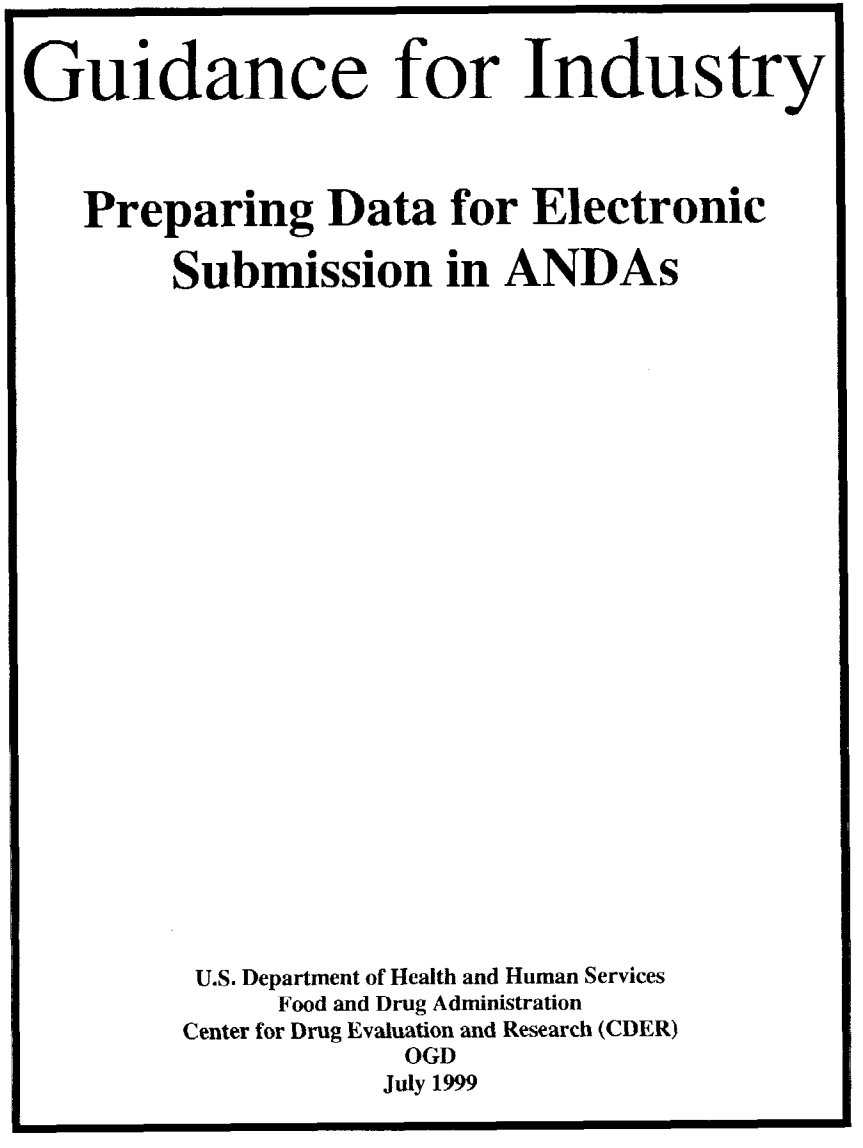
Guidance & Future Direction



Richard Sponaugle

Senior Systems Engineer,
OGD Electronic
Submission Project,
CDER - FDA

Electronic Abbreviated New Drug Applications



Level Two Guidance:

- **Addresses both CMC and bioequivalence**
- **Covers the program as it now exists**
- **Will be updated as we move to paperless submissions**

Available at:
http://www.fda.gov/cder/guidance/index.htm

Electronic Abbreviated New Drug Applications

This guidance is intended to provide assistance to applicants submitting data in electronic format to the Office of Generic Drugs (OGD) in abbreviated new drug applications (ANDAs). This guidance should be used in conjunction with the entry and validation application (EVA) user's manual, available on OGD's electronic submission web site.

When OGD is prepared to archive electronic ANDAs, a guidance will be developed consistent with the Agency's good guidance practices policy (62 FR 8961, February 27, 1997). At that time, information from this guidance will be incorporated into the Agency guidance on electronic regulatory submissions.

Electronic Abbreviated New Drug Applications

What's Covered?

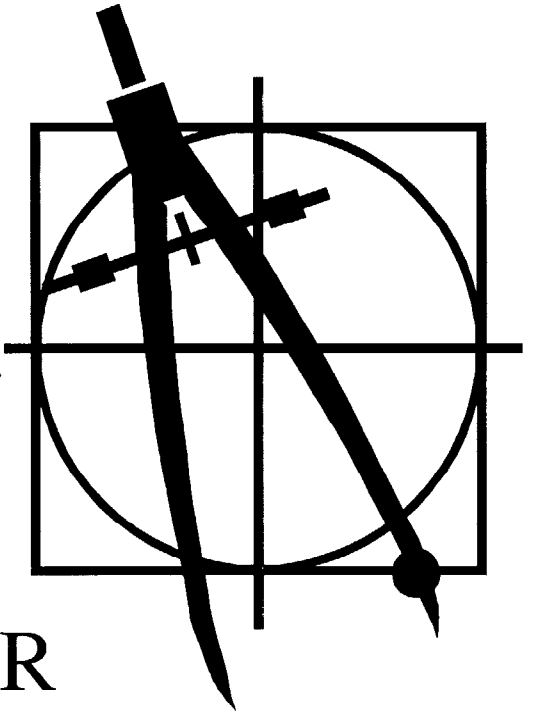
- Basic Rules of Participation
- How to Prepare the Media for Submission
- Where to Send the Submission
- Electronic Submission Tips and Suggestions
- How to Get Additional Help

What's Not?

- Detailed Instructions for Using EVA

The Future of Electronic Submissions in OGD

What We Have Now, Only Better!!



- Continued refinement of the structured data elements.
- The addition of a PDF component
- Paperless Archive
- Updates to Existing Guidances
- Web site will be migrated to CDER
- Training will continue to be available at the University of Maryland

The Future of Electronic Submissions in OGD

Continued refinement of the structured data elements.

A little fine tuning here and there

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NOT AN OVERHAUL

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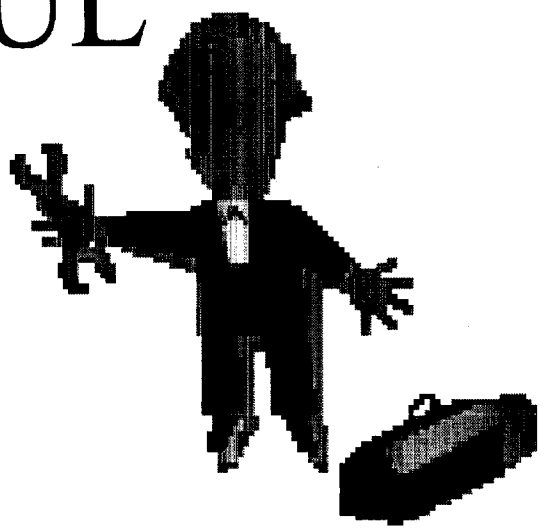


As we continue to gain experience with the electronic submission system we discover some elements we would like to add to the structured submission and some that we would like to remove.

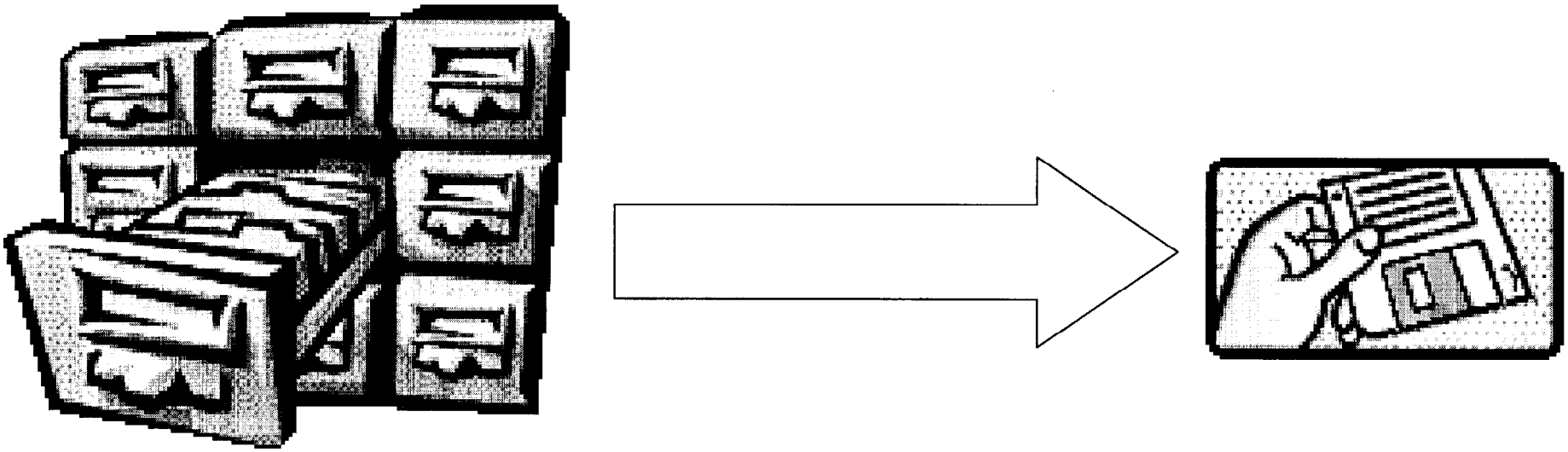
The Future of Electronic Submissions in OGD

The addition of a PDF component -Paperless Archive

An acronym for Portable Document Format, PDF is a file type created by Adobe Systems, Inc. that allows fully formatted, high-resolution, PostScript documents to be easily transmitted across the Internet and viewed on any computer that has Adobe Acrobat Reader software (a proprietary viewer is available for free at the Adobe site).

The Future of Electronic Submissions in OGD

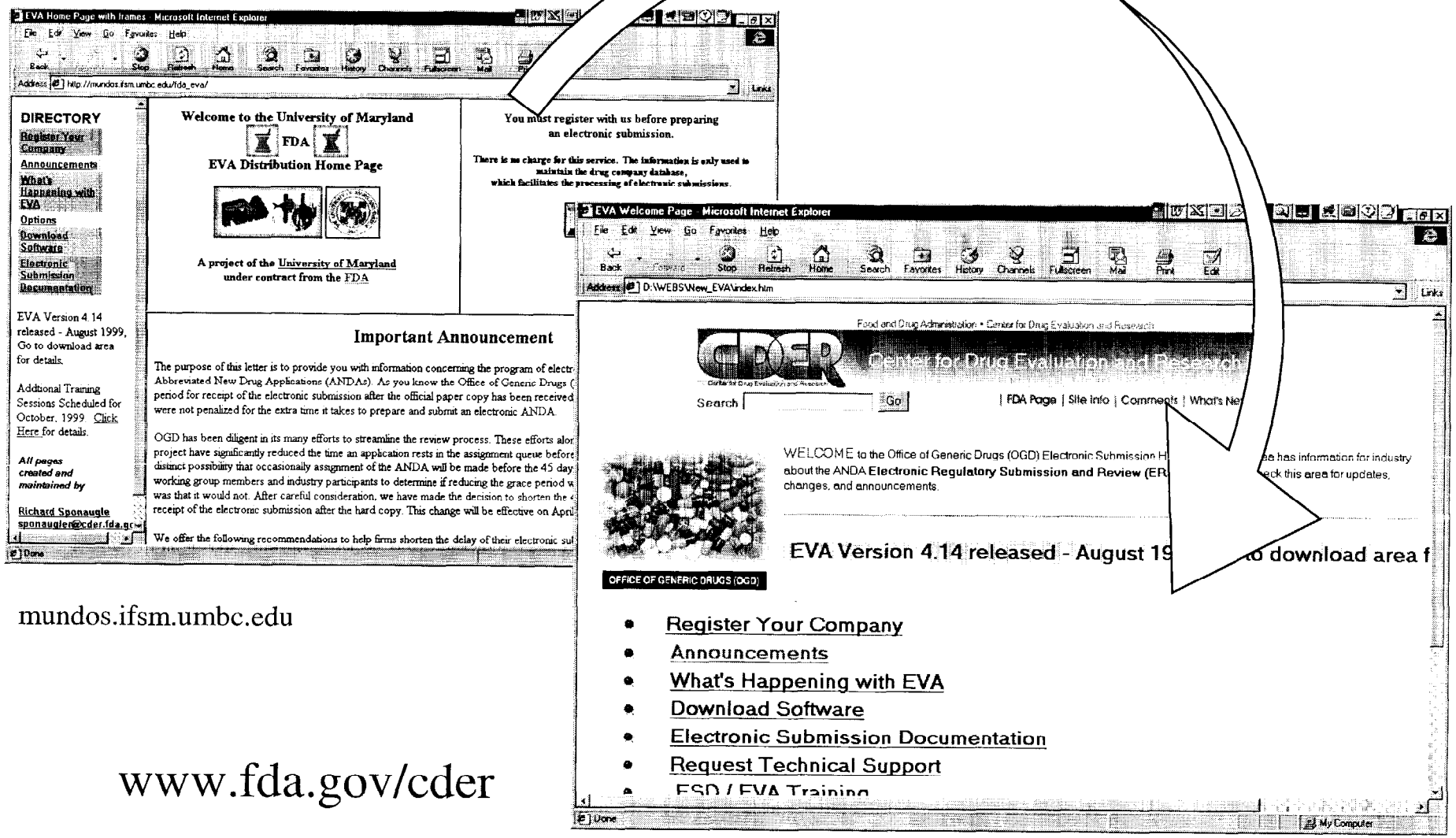
Why Paperless Archive?



Being able to submit and receive information in electronic format in an ANDA is expected to yield many benefits to industry and FDA, including a more consistent submission, a more consistent and rapid review, and a **reduction in archiving and storage space**.

The Future of Electronic Submissions in OGD

Web site will be migrated ~~to CDER~~

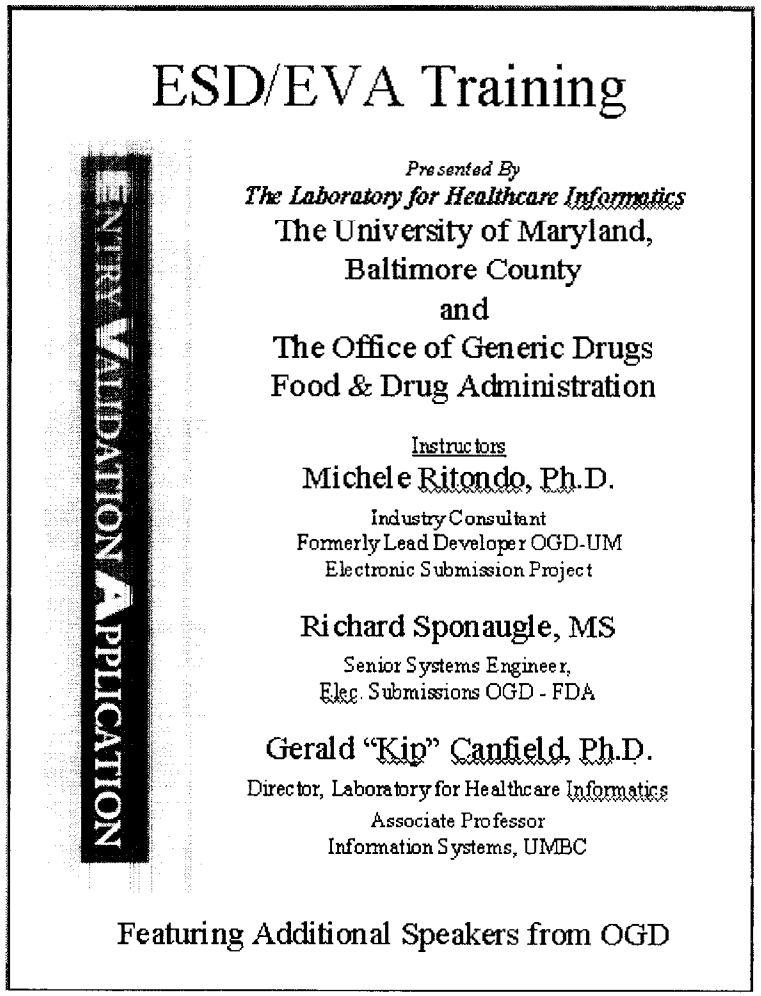


mundos.ifsm.umbc.edu

www.fda.gov/cder

The Future of Electronic Submissions in OGD

Training will continue to be available at the University of Maryland, Baltimore County



Under a cooperative agreement with the FDA, UMBC will continue to offer periodic training sessions covering the preparation of electronic ANDAs.

Additional information available at:
http://lhi5.umbc.edu/fda/